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(54) Title: PURIFIED SUBFRAGMENT CODIFYING FOR NEUROAMINIDASE, RECOMBINANT NEUROAMINIDASE AND ITS USE IN ZOOPROPHYLAXIS

(57) Abstract: Within the prophylaxis strategies for the control of type A avian influenza caused by viral infection with specific epidemic strain H7N1, a vaccination process is envisaged comprising the preparation of a heterologous vaccine that is administered to an animal population, said vaccine featuring the same subtype of viral haemoagglutinin HA7 and a different subtype of neuroaminidase NA3, and thereafter detecting the viralinfection positiveness by contacting an antigen with at least one genomic sequence that codes for a neuroaminidase NA1 protein with the biological fluids collected from the animals. By subsequently revealing an antigen-antibody reaction by means of a test for detecting positiveness (iIFA, ELISA among others), the vaccinated animals can be discriminated from the other ones. The recombinant antigen is represented by the recombinant glycoprotein neuroaminidase NA1, the genomic sequence of which is carried by a baculovirus and expressed in insect cell.

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A. CLASSIF IPC 7	FICATION OF SUBJECT MATTER A61K39/295 G01N33/569 A61K39/14	45					
Aording to	International Patent Classification (IPC) or to both national classificat	tion and IPC					
B. FIELDS							
Minimum do	cumentation searched (dassification system followed by classification	n symbols)					
IPC 7	A61K						
Documentat	ion searched other than minimum documentation to the extent that su	och documents are included in the fields se	arched				
Electronic da	ata base consulted during the international search (name of data base	e and, where practical, search terms used					
BIOSIS	BIOSIS, EPO-Internal, MEDLINE, EMBL						
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT						
Category °	Citation of document, with indication, where appropriate, of the rele	want passages	Relevant to claim No.				
X	DATABASE EMBL 'Online! 15 December 1999 (1999-12-15) LEE M S ET AL: "Influenza A virus (A/chicken/Taiwan/7-5/99 (H6N1))	seament 6	1				
	neuraminidase gene, complete cds"	ocgment c					
	retrieved from EMBL Database accession no. AF208598						
	XP002229091 the whole document						
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X	US 6 221 362 B1 (RIVIERE MICHEL 24 April 2001 (2001-04-24) column 13, line 9 - line 28; figu		3,4				
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X Furt	her documents are listed in the continuation of box C.	Patent family members are listed	in annex.				
° Special ca	ategories of cited documents:	"T" later document published after the inte or priority date and not in conflict with					
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"O" docum	n or other special reason (as specified) ent referring to an oral disclosure, use, exhibition or	cannot be considered to involve an in- document is combined with one or mo- ments, such combination being obvior	ore other such docu-				
P docume	means ent published prior to the international filing date but han the priority date claimed	In the art. *&* document member of the same patent					
	actual completion of the international search	Date of mailing of the international sea	arch report				
2	9 January 2003	17/02/2003					
Name and	mailing address of the ISA	Authorized officer					
	European Patent Office, P.B. 5818 Patentlaan 2 NL 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,	Turri, M					
1	Fax: (+31-70) 340-3016	'''' '''					

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PCT/IT 02/00231

	PC1/11 02/00231				
	C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
X	JOHANSSON B E: "Immunization with influenza A virus hemagglutinin and neuraminidase produced in recombinant baculovirus results in a balanced and broadened immune response superior to conventional vaccine" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 17, no. 15-16, 9 April 1999 (1999-04-09), pages 2073-2080, XP004165058 ISSN: 0264-410X	5-23,28			
Y	the whole document	17, 24-27, 29-31			
	See especially pages 2074-2075, "Methods"				
Y	CAPUA LDARIA ET AL: "Strategies for the control of avian influenza in Italy." THE VETERINARY RECORD. ENGLAND 16 FEB 2002, vol. 150, no. 7, 16 February 2002 (2002-02-16), page 223 XP009004791 ISSN: 0042-4900 the whole document See especially the second paragraph of the article	17, 24-27, 29-31			
Α	PRICE P M ET AL: "COMPLEMENTATION OF RECOMBINANT BACULOVIRUSES BY COINFECTION WITH WILD-TYPE VIRUS FACILITATES PRODUCTION IN INSECT LARVAE OF ANTIGENIC PROTEINS OF HEPATITIS B VIRUS AND INFLUENZA VIRUS" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE. WASHINGTON, US, vol. 86, no. 5, 1 March 1989 (1989-03-01), pages 1453-1456, XP000008241 ISSN: 0027-8424 the whole document				
Α	JOHANSSON B E ET AL: "Immunogenicity of influenza A virus N2 neuraminidase produced in insect larvae by baculovirus recombinants" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 13, no. 9, 1 June 1995 (1995-06-01), pages 841-845, XP004057540 ISSN: 0264-410X				

Intermonal Application No
PCT/IT 02/00231

	INTERNATIONAL SEAROTTREFORT	PCI/II	02/00231
C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	•	
Category °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
A	SUAREZ D L ET AL: "Immunology of avian influenza virus: A review." DEVELOPMENTAL & COMPARATIVE IMMUNOLOGY, vol. 24, no. 2-3, March 2000 (2000-03), pages 269-283, XP002229027 ISSN: 0145-305X		
A	SWAYNE D E ET AL: "Highly pathogenic avian influenza." REVUE SCIENTIFIQUE ET TECHNIQUE OFFICE INTERNATIONAL DES EPIZOOTIES, vol. 19, no. 2, August 2000 (2000-08), pages 463-482, XP001122269 ISSN: 0253-1933		
A	SUAREZ DAVID L: "Evolution of avian influenza viruses." VETERINARY MICROBIOLOGY, vol. 74, no. 1-2, 22 May 2000 (2000-05-22), pages 15-27, XP002229029 ISSN: 0378-1135		

Interconal Application No PCT/IT 02/00231

Patent document cited in search report		Publication date	•	Patent family member(s)	Publication date
US 6221362	B1	24-04-2001	FR	2751225 A1	23-01-1998
			AU	735184 B2	05-07-2001
			AU	3773697 A	10-02-1998
			BR	9710495 A	17-08-1999
			CN	1225685 A	11-08-1999
			EP	0914442 A1	12-05-1999
			WO	9803659 A1	29-01-1998
			JP	2001503019 T	06-03-2001
			NZ	333779 A	28-07-2000
			US	2002037292 A1	28-03-2002